FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Policy Analysts and Regulatory Counsel *who will develop regulations, guidances, policies, and procedures concerning medical device and radiation-emitting products.*

Working as a *Policy Analyst*, you may:

- Draft guidance documents and other policy documents within CDRH
- Draft supporting statements for information collection requests as required per the Paperwork Reduction Act (PRA) for regulations, guidance documents and/or other requests for information (e.g., surveys)
- Write supporting statements and required documents for publication in the Federal Register
- Lead work groups and coordinate with other Centers and Offices within the FDA
- Analyze public comments on regulatory documents and implement appropriate revisions
- Develop standards and coordinate activities of accreditation bodies as part of the Center's conformity standards accreditation program

To be considered for the *Policy Analyst* role, here are the skills and experience we're looking for:

- Expertise in medical device law, including but not limited to, the Federal Food, Drug, and Cosmetic (FD&C) Act, the Public Health Service Act, the Medical Device User Fees Amendments and subsequent amendments, etc.
- Ability to apply and interpret policies, procedures, regulations, and statutory provisions (e.g., FD&C Act, Paperwork Reduction Act)
- Skill in effectively interpreting and presenting complex information and concepts, in both written and oral formats
- Ability to lead working groups and work effectively and collaboratively within diverse teams

Working as *Regulatory Counsel*, you will apply your legal expertise to:

- Develop regulations, policies, and programs involving complex and high priority matters affecting the regulation of medical devices and radiological health products
- Provide advice on the impact of recently enacted legislation, interpreting, analyzing, and providing advice on laws relevant to medical devices and radiological health products
- Analyze the impact of existing or proposed legislation on FDA regulations, and policies
- Interpret and apply existing policies, setting precedents that affect internal and industry program activities and the marketing of regulated products in which CDRH has jurisdiction

To be considered for the *Regulatory Counsel* role, here are the skills and experience we're looking for:

- Expertise in medical device law, including but not limited to, the Federal Food, Drug, and Cosmetic (FD&C) Act, the Public Health Service Act, the Medical Device User Fees Amendments, and subsequent amendments, etc.
- Ability to draft complex documents, reports, memoranda, briefs, and press releases related to regulatory requirements; opinions and responses to citizen petitions; petitions for stay of action; and/or petitions for reconsiderations for a variety of audiences
- Skill in effectively interpreting and presenting complex information and concepts, in both written and oral formats
- Ability to lead working groups and work effectively and collaboratively within diverse teams